REMARKS

Election/Restriction

The Examiner has required Applicant to confirm the election of species B, claim 6 in its Response to the present Office Action. Such election is hereby confirmed and Applicant identifies claim 6 as the only claim readable thereon.

Specification

The Abstract has been objected to for various informalities. Applicant submits herewith a replacement Abstract to obviate the noted objections.

Claim Objections

Claim 2 has been objected to for inconsistent language from parent claim 1. Claim 1 has been amended to use consistent terminology as recommended by the Examiner.

35 U.S.C. § 112 Rejections

Claims 2-3 and 9 have been rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 2 was rejected on the basis of the lack of clarity with respect to the structure defining the ports. Claim 2 has been amended to clarify that the pointed tip end defines a central port. Applicant submits that this amendment obviates the present rejection of claim 2.

Claim 3 has been rejected for lack of antecedent basis for the phrase "said side ports" in view of claim 2 reciting "at least one side port." Applicant submits that the amendment to claim 2 to remove the phrase "at least one side port" obviates the present rejection of claim 3.

Claim 9 has been rejected for insufficient antecedent basis for the limitation "said sensor" and appears to have been intended to depend from claim 8 instead of claim 1. The dependency has been corrected in the current

amendments to the claims. Applicant submits that the amendment obviates the present rejection of claim 9.

35 U.S.C. § 102(e) Rejections

Claims 1-3, 6-9, 12-14, 16-19, 22 and 25 have been rejected under 35 USC § 102(e) as allegedly being anticipated by Haar et al. (US Patent No. 6,584,335). In responding to this rejection, Applicant is treating this rejection as a rejection under 35 USC 102(b) in view of the PCT Publication of Haar et al. on February 18, 1999, thereby mooting Applicant's ability to antedate Haar et al. via 37 CFR 1.131 Declaration establishing prior invention.

Applicant respectfully submits that all of the independent claims (1, 16, 22 and 25) currently amended, or originally filed in the case of claim 22, are not anticipated nor rendered obvious by Haar et al. Specifically, Applicant submits that the claims as amended (where necessary) clarify a feature of the invention not taught or suggested by Haar et al. Specifically, all of the independent claims include the feature of the invention whereby electromagnetic radiation, such as light, is carried to one of the ports on the needle for irradiating an area adjacent the port. In other words, the light is shined outside the needle body by a fiber optic member disposed in a port and then backscattered radiation is received and carried via a fiber optic member or members disposed in at least another of said ports on the needle to a detector for detecting the backscattered light.

By stark contrast to Applicant's disclosure of this aspect of the invention, Haar et al. teaches the use of a single fiber optic element that has an inbound fiber optic track 20, 25 and a return fiber optic track 21, 26. *See* Col. 7, lines 22-44. The tracks are disposed inside the needle body and do **not** irradiated areas outside the needle body. This is the antithesis of Applicant's invention. Specifically, with respect to every embodiment, the fiber optic tracks are configured to ensure that all of the light sent down the incoming track is fed into the return track as opposed to irradiating areas adjacent the needle:

> In the embodiment shown, two parallel optical fiber tracks run in the fiber optic cable 11 within a flexible jacket 12. The measuring light from the beam combiner 10 is coupled into the first (inbound) fiber optic

> track 25 of the cable 11 and further guided into the inbound fiber track 20 of the measuring probe 3. Following reflection at reflector 24, the measuring light is guided back through the return fiber track 21 of the measuring probe 3 and through an associated return fiber track 26 of the fiber optic cable 11 and into the electronics unit 5, where it is detected by a detector 27.

Col. 7, lines 29-38. In making the rejection, the Examiner identifies element 24 as a "central port" thereby suggesting that light is emitted out of the needle end to irradiate the adjacent area. However, as clearly set forth in the specification, element 24 as depicted in Figs. 3 and 4 does not emit, but rather, reflects light.

A similar discussion of reflecting light up to the return optic track is discussed in connection with Fig. 5 and the use of a "reflecting cap 40"

> The deflection of the light proximate the distal end 23 of the hollow needle 18 is effected here with a narrow deflection loop 39 in a continuous optical fiber 22. In contrast to reference 4), the region of the deflection loop 39 is not used for measurement. On the contrary, a reflecting cap 40 makes sure that the light is deflected with as low reflection losses as possible and does not couple out.

Col. 9, lines 26-32. As clear from the foregoing, Haar et al. is teaching the exact opposite of Applicant's claimed invention. The reason Haar et al. is reflecting light up the return optic track is because Haar et al. is not measuring backscattered light but rather measuring wavelength dependent attenuation in the measuring section of the needle caused by the presence of a specific analyte. *See* Col. 3, lines 64-67. The mechanism in operation, interaction between the fiber optic return track and the analyte as opposed to measuring backscattered radiation is clearly set forth in the specification:

> The measuring section of the hollow needle is sufficiently permeable to the interstitial liquid that the interaction of the light transported in the optical fiber with the analyte which is required for the analysis takes place in the measuring section. Within the context of the invention, it has been discovered that, with the very small dimensions of the hollow needle, diffusion exchange of the analyte between the interstitial liquid surrounding the hollow needle and the surface of the optical fiber in the measuring section is sufficient to allow monitoring of the physiological changes of important analytes, in particular glucose, with high precision. The permeability of the hollow needle must be adapted to this

> requirement. In the preferred case of a metallic hollow needle, the permeability is effected by appropriate perforations.
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> A preferred measurement principle is based on the interaction between the light and the analyte in the measuring section caused by the penetration of an evanescent field into the liquid, in particular based on ATR spectroscopy. Thus the wavelength dependent attenuation in the measuring section is the modification of the light transported in the optical fiber which is characteristic of the presence of the analyte. Concerning suitable measurement and evaluation procedures, reference is made to the complete disclosure of the relevant literature, in particular to the publications cited above.

Col. 3, ln 33-47, Col. 3, ln 61 to Col. 4, ln 3. The Haar et al. specification not only fails to anticipate Applicant's claimed invention, but also clearly teaches away from the use of fiber optics to irradiate an area outside the needle. *In re Dulberg,* 129 USPQ 348, 349 (CCPA 1961). A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Assoc., Inc. v. Garlock, Inc.* 220 USPQ 303 (Fed. Cir. 1983).

In order to maintain a rejection under 35 U.S.C § 102, each and every limitation must be disclosed in a single reference. Accordingly, Applicant submits that the outstanding rejection of the independent claims under 35 U.S.C. § 102 is proper and such action is respectfully requested. Also, by definition, if an independent claim is not anticipated by the prior art, any claim depending therefrom cannot be anticipated. Accordingly, Applicant respectfully requests withdrawal of the dependent claims under 35 U.S.C. § 102 as set forth in the Office Action.

35 U.S.C. § 103 Rejections

To establish a prima facie case of obviousness, all of the claim limitations must be taught or suggested by the prior art. *In re Royka*, 180 USPQ 580 (CCPA 1974): MPEP § 2143.05. Moreover, if an independent claim is non-obvious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious. *In re Fine,* 5 USPQ.2d 1596 (Fed. Cir. 1988). With respect to the

rejection of claims under 35 U.S.C. § 103, Applicant respectfully submits that none of the references overcome the deficiencies in the Haar et al. reference as set forth above. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the outstanding rejections of the claims under 35 U.S.C. §103.

CONCLUSION

This application is in condition for allowance and early notice of the same is respectfully requested. Should the Examiner have any questions, comments or suggestions, he is invited to contact Applicant's representative at tehe number indicated below.

Respectfully submitted,
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By: _____

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